

10/500228  
DT04 Rec'd PCT/PTO 25 JUN 2004

AMENDMENTS TO THE CLAIMS

Please replace all prior versions of the claims with the following claim listing:

***Claims:***

1. (Currently Amended) An expandable intra-gastric balloon (1) for treating obesity, ~~for implanting~~ implanted in the stomach of a patient to reduce the volume of the stomach, said balloon (1) comprising:

a first flexible pouch (2) defining a predetermined inside volume, said first flexible pouch (2) being provided with first connection means (3) including an orifice (4) and a valve (5) for receiving a connection member (6) for connection to a first fluid source in order to expand said first pouch (2) in the stomach by filling it with the fluid[[,]] ; ~~and the balloon being characterized in that it includes~~

at least one second flexible pouch (20) of predetermined volume and provided with second connection means (3') with an orifice (4') and a valve (5'), said second connection means (3') being separate from the first connection means (3) so as to be capable of being connected to a second fluid source different from the first fluid source.

2. (Currently Amended) ~~A~~ The balloon according to claim 1, ~~characterized in that~~ wherein said at least one second pouch (20), of volume smaller than that of the first pouch (2), is disposed inside the first pouch (2).

3. (Currently Amended) ~~A~~ The balloon according to claim 2, ~~characterized in that~~ wherein said at least one second pouch is disposed substantially concentrically with the first pouch (20).

4. (Currently Amended) ~~A~~ The balloon according to claim 2 ~~or claim 3,~~ ~~characterized in that~~ wherein the orifices (4, 4') are substantially in alignment, so as to be capable of receiving a common connection member (10A).

5. (Currently Amended) ~~A~~The balloon according to ~~any one of claims 2 to 4, characterized in that it includes~~claim 2, the balloon further comprising spacer means (10, 10A) for holding said at least two pouches (2, 20) respectively at a distance apart from each other.

6. (Currently Amended) ~~A~~The balloon according to claim 5, ~~characterized in that~~wherein the spacer means (10, 10A) are formed by spacers holding and fixing the two pouches (2, 20) at a distance from each other.

7. (Currently Amended) ~~A~~The balloon according to claim 6, ~~characterized in that it includes two~~wherein the spacers (10, 10A) that are substantially diametrically opposite each other about the common center of the two pouches (2, 20).

8. (Currently Amended) ~~A~~The balloon according to claim 6 ~~or claim 7, characterized in that,~~ wherein the spacers (10, 10A) are formed by two base plates interconnected by a leg (11), each base plate being fixed, ~~e.g. by adhesive,~~ to a respective one of the first and second pouches.

9. (Currently Amended) ~~A~~The balloon according to ~~any one of claims 5 to 8, characterized in that~~ claim 5, wherein the first and second connection means (3, 3', ~~10A~~) are common to the two pouches and are formed by one of the spacers.

10. (Currently Amended) ~~A~~The balloon according to claim 9, ~~characterized in that~~wherein the common connection means (10A) comprises a hollow central duct (21) formed by the leg (11) of the spacer (10), said duct having two holes (22, 23), each in register with the inside volume of a respective one of the first and second pouches (2, 20), and each being associated with a respective valve (5, 5'), said duct being suitable for receiving a connection member (6) for differentially filling each of the pouches (2, 20) with a distinct filler fluid.

11. (Currently Amended) ~~A~~The balloon according to ~~any one of claims 1 to 10, characterized in that~~ claim 1, wherein the first pouch (2) is filled with a liquid, the second pouch (20) being filled with a gas.

12. (Currently Amended) ~~A~~The balloon according to ~~any one of claims 1 to 11, characterized in that~~ claim 1, wherein the outside surface of the balloon is subdivided into cells (2C).

13. (Currently Amended) A surgical device for treating obesity, the surgical device serving to expand an intra-gastric balloon itself comprising a first pouch (2) and a second pouch (20) disposed inside the first pouch (2), the pouches having respective orifices (4, 4') arranged to receive a common connection member (10A) in the stomach of a patient, said surgical device comprising:

a tubular connection member (6) suitable for being inserted in a hollow central duct (21) of the common connection ~~means~~member (10A) of the intra-gastric balloon, said tubular connection member being provided with two independent channels (15, 16) each having a respective end opening out in register with a corresponding one of two holes (22, 23) in the central duct (21), and each having its opposite end connected to a respective independent endpiece (17, 18) suitable for being connected to distinct filler fluid sources.

14. (Currently Amended) ~~A~~The surgical device according to claim 13, ~~characterized in that~~wherein the two channels (15, 16) are concentric.

15. (Currently Amended) A method of fabricating an intra-gastric balloon comprising a first pouch and a second pouch disposed inside the first pouch, the pouches having respective orifices arranged to receive a common connection member, ~~in which the method, the following steps are performed~~ comprising:

· fabricating first and second pouches by injecting elastomer material in a mold to obtain at least two pouches each having a respective orifice, the first pouch being of dimensions greater than those of the second pouch; and

- during the step of fabricating the first pouch or thereafter, placing a spacer on the outside face of the first pouch substantially opposite from its orifice, the spacer presenting a free outer base plate; ~~then~~

- bonding the two pouches together at the free outer base plate by using adhesive between said base plate and the outside face of the second pouch, substantially opposite from its orifice; and ~~then~~

- turning the first pouch inside out, causing the second pouch to penetrate therein via its orifice.

16. (Currently Amended) ~~A~~The method according to claim ~~14~~15, ~~characterized by~~further comprising subsequently placing the common connection ~~means-member~~ of the two pouches in the two substantially aligned orifices of the first and second pouches, and bonding said common ~~means~~connection member thereto via its two base plates.

17. (Currently Amended) An intra-gastric balloon (1) for treating obesity, ~~for implanting~~implanted in the stomach (31) of a patient in order to reduce the volume of the stomach, said balloon (1) comprising:

an outside wall (2A) for coming into contact with the wall (30) of the stomach (31), the balloon (1) subdividing the stomach (31) into an upstream zone (31A) and a downstream zone (31B) in order to constitute a barrier for the passage of food between these two zones[[,]];

wherein the outside wall (2A) ~~being~~is shaped so as to co-operate with the wall (30) of the stomach to define channels (32) for passing food from the upstream zone (31A) to the downstream zone (31B)[[,]]; and

~~the balloon being characterized in that~~ wherein the outside wall (2A) is shaped so that the channels (32) form a network branching at more than two points, so as to constitute a path of tree structure for food passing from the upstream zone (31A) to the downstream zone (31B).

18. (Currently Amended) ~~A~~The balloon (1) according to claim 17, ~~characterized in that wherein~~ the outside wall (2A) has a plurality of projections (33) arranged relative to one another in such a manner that the channels (32) are defined firstly by the interstices between the projections (33) and secondly by the wall (30) of the stomach (31) in contact with the tops (34) of said projections (33).

19. (Currently Amended) ~~A~~The balloon (1) according to claim 18, ~~characterized in that wherein~~ each projection (33) projects from a substantially polygonal base, the polygonal bases touching one another over at least a fraction of the surface of the outside wall (2A).

20. (Currently Amended) ~~A~~The balloon (1) according to claim 19, ~~characterized in that wherein~~ the projections are arranged relative to one another in a truncated icosahedron pattern.

21. (Currently Amended) ~~A~~The balloon (1) according to ~~any one of claims 17 to 20, characterized in that it is constituted by~~claim 19, further comprising a flexible pouch that is expandable by being filled with fluid, the pouch being constituted by an envelope whose outside face forms the outside wall (2A).

22. (Currently Amended) ~~A~~The balloon (1) according to ~~claims 21 and 19 or according to claims 21 and 20, characterized in that~~claim 21, wherein the envelope is formed by assembling the polygonal bases via their sides (32A), the core (33) of each base being more flexible than the sides (32A) of each base, such that during inflation of the pouch by being filled with fluid, the core (33) of each base deforms more than the sides (32A), thus having the effect of generating protuberances that form the projections (33).

23. (Currently Amended) ~~A~~The balloon (1) according to claim 22, ~~characterized in that~~wherein the envelope is made of an elastomer material such that the core (33) of each base is of smaller thickness than the sides, thereby obtaining different flexibility between the core (33) and the sides (32A) of each base.

24. (Currently Amended) ~~A~~The balloon (1) according to claim 23, ~~characterized in that~~wherein the envelope is made by associating a fabric presenting a mesh forming the sides (32A) of the bases, with an elastomer film forming the core (33) of each base, the mesh being less deformable than the elastomer film.

25. (Currently Amended) An intra-gastric balloon (1) for treating obesity, for implanting in the stomach of a patient to reduce the volume of the stomach, said balloon (1) comprising a flexible envelope (2) defining a predetermined inside volume, said flexible envelope (2) being made of an elastomer material, ~~the balloon being characterized in that~~wherein the dimensional tolerance (T) on the nominal thickness ( $e_{nom}$ ) of the envelope lies in the range of 1% to 20%.

26. (Currently Amended) ~~An~~The intra-gastric balloon (1) according to claim 25, ~~characterized in that~~wherein the tolerance (T) lies in ~~at~~the range of 10% to 16%.

27. (Currently Amended) ~~An~~The intra-gastric balloon according to ~~claim 25 or claim 26, characterized in that~~claim 25, wherein the nominal thickness ( $e_{nom}$ ) of the envelope (2) is substantially equal to 0.5 mm, with tolerance (T) lying in the range of 10% to 16%.

28. (Currently Amended) ~~An~~The intra-gastric balloon (1) according to ~~any one of claims 25 to 27, characterized in that~~claim 25, wherein the envelope (2) is made of silicone, or is based on silicone.

29. (Currently Amended) A method of fabricating an intra-gastric balloon (1) for treating obesity, said balloon (1) ~~being for implanting~~designed to be implanted in the stomach of a patient in order to reduce the volume of the stomach, the method comprising:

~~being characterized in that it includes an injection step in which~~injecting an elastomer material ~~is injected~~ into a mold in order to obtain a flexible pouch that is to ~~from the form an~~ envelope (2) on the balloon (1).

30. (Currently Amended) ~~A~~The method according to claim 29, ~~characterized in that wherein, prior to the injection step, it includes a step of the~~ method comprises:

preparing a mold in which a top cavity (40) of generally hemispherical shape is pressed against a bottom cavity (41) likewise of generally hemispherical shape, so as to obtain an inside volume that is substantially spherical in shape, with a spherical core (42) being previously positioned between the two cavities (40, 41), concentrically therewith, the diameter of the core being smaller than the diameter of said inside volume[.,.]; and

wherein the injection step comprising a step of injecting the elastomer material into the space (43) that extends between the core (42) and the cavities (40, 41) so as to obtain a pouch of generally spherical shape that is to form the envelope (2) of the balloon.